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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,959	03/07/2000	Nancy Carrasco	96700/488	9663

7590 10/02/2002

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	109

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/519,959	CARRASCO ET AL.
	Examiner	Art Unit
	Stephen L. Rawlings, Ph.D.	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 July 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-9 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-9 and 29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicants' submission filed on July 10, 2002 has been entered.
2. The amendment filed on April 12, 2002 in Paper No. 14 has been entered. Claims 3, 10, and 11 have been canceled. Claims 1, 7, and 8 have been amended. Claim 29 has been added.
3. The amendment filed on July 10, 2002 in Paper No. 18 has been entered. Claim 1 has been amended.
4. Claims 1, 2, 4-9, and 29 are pending in the application and are currently under prosecution.

Grounds of Claim Rejections Withdrawn

5. Unless specifically reiterated below, the grounds of claim rejections set forth in previous Office actions have been withdrawn.

Claim Rejections Maintained and Response to Applicants' Remarks

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Cancroft, et al (*Radiology* **106**: 441-444, 1973), as evidenced by Socolow, et al (*Endocrinology* **80**: 337-344, 1967), Tazebay, et al (*Nature Medicine* **6**: 871-878, 2000), Spitzweg, et al (*Journal of Clinical Endocrinology* **83**: 1746-1751, 1998), and Eskandari, et al (*Journal of Biological Chemistry* **272**: 27230-27238, 1997) essentially for the reason stated in the previous Office actions.

The claims are drawn to a method of detecting the presence or absence of breast cancer in a non-lactating subject, said method comprising determining the expression of mammary gland sodium/iodide symporter (mgNIS) in the breast tissue of the subject, wherein the expression of the symporter is detected *in vitro* or *in vivo* using an agent that binds mgNIS.

As stated in the previous Office actions, Cancroft, et al teach a method for differentiating benign and malignant masses in the breast tissue of a subject. The method of Cancroft, et al comprises administering ^{99m}Tc-pertechnetate to the subject, which is an agent transported into the cell via mgNIS by a mechanism involving binding of the agent to the transporter.

Eskandari, et al propose that the mechanism by which the thyroid gland sodium/iodide symporter (tgNIS) transports substrate, e.g., iodide, ^{99m}Tc-pertechnetate, and most other monovalent anions involves binding of the anion to the symporter. The mechanism by which mgNIS transports anions such as ^{99m}Tc-pertechnetate is deemed the same as the mechanism by which tgNIS, absent a showing of any difference. Accordingly, the agent of the prior art is deemed the same as the agent of the instant claims, absent a showing of any difference. As noted in previous Office actions, the Office does not have the facilities for examining and comparing the mechanistic features of Applicants' method with those of the method of the prior art in order to establish that the method of the prior art does not possess the mechanistic features as the claimed invention. Furthermore, in the absence of evidence to the contrary, the burden is upon

Applicants to prove that the claimed method is mechanistically different than that taught by the prior art and to establish patentable differences.

Applicants' arguments have been carefully considered and addressed in previous Office actions. Again, these arguments have not been found persuasive. Accordingly, upon the basis of the preponderance of evidence, the rejection of claims 1 and 2 under 35 USC § 102(b) for the reason set forth in the previous Office Action is maintained.

New Grounds of Claim Objections

8. Claims 4-6 are objected to as being in improper because the claims depend from a canceled claim. Accordingly, claims 4-6 have not been further treated on the merits.

New Grounds of Claim Rejections

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 7-9 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 7-9 and 29 are drawn to the method of claim 1 wherein the expression of mgNIS is detected using at least one nucleic acid probe.

The teachings of the specification cannot be extrapolated to the enablement of the claimed invention because a nucleic acid probe is not expected to bind to mgNIS, and the method has not been exemplified.

Absent a showing commensurate in scope with the claims, the skilled artisan would not accept the assertion that the invention could be used to detect the presence or absence of breast cancer in a subject. Moreover, given only the benefit of

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Applicants' disclosure, one skilled in the art would not be able to practice the invention with a reasonable expectation of success without the need to perform additional, undue experimentation. Accordingly, the specification does not disclose a sufficient amount of guidance, direction, and exemplification to meet the requirements set forth under 35 USC § 112, first paragraph.

Conclusion

11. No claims are allowed.

12. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure. Reidel, et al review the iodide transporter NIS.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

slr
September 30, 2002